Remarks

Claims 1-46 are pending in the subject application. By this Amendment, Applicants have amended claims 1, 4, 11, 15, 16, 30, and 40. Support for the amendments can be found throughout the subject specification. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 1-46 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

As an initial matter, Applicants have attached replacement pages 21 and 24 of the subject specification to correct the overlapping text and spacing alignment at line 24 of page 21 and at line 3 of page 24. In addition, Applicants have attached replacement pages 34-37 to correct inadvertent typographical errors in the References section of the subject specification. Entry of new pages 21, 24, and 34-37 in the specification is respectfully requested. Applicants respectfully assert that no new matter is included in these replacement pages.

Claims 1-46 are rejected under 35 USC §103(a) as obvious over published PCT application WO 94/02613. Under this rejection, the Examiner indicates that the WO 94/02613 publication discloses FIV and the development of vaccines for use in protecting cats and kittens against FIV infection. The Examiner concludes that it would have been obvious at the time of the present invention for an ordinarily skilled artisan to induce an immune response to FIV in a human or an animal that is susceptible to infection by FIV "because that is what 'FIV vaccine' does." The Examiner further asserts that the method of inducing such an immune response, regardless of whether it is for a human or any other animal, is already disclosed in the WO 94/02613 publication. Applicants respectfully traverse this grounds of rejection.

Applicants respectfully assert that the WO 94/02613 publication does not teach or suggest Applicants' claimed invention. As an initial matter, Applicants note that the Examiner indicates the invention claimed in the subject application is "directed to a method for inducing an immune response to a feline immunodeficiency virus in a human or an animal susceptible to infection by FIV." However, while claims 1-7 are directed to "a method for inducing an immune response to a feline immunodeficiency virus (FIV) in a human or an animal that is susceptible to infection by FIV . . .," Applicants note that claims 8-14 are directed to "a method for inducing an immune response to a human immunodeficiency virus (HIV) in a human, said method comprising

administering an effective amount of an FIV immunogen . . .." Claims 15-28 are directed to "a method for treating or preventing feline immunodeficiency virus (FIV) infection in a human or an animal that is susceptible to infection by FIV . . .." Claims 29-34 are directed to "a method for treating or preventing infection by human immunodeficiency virus (HIV) in a human, . . . comprising administering an FIV immunogen . . .." Claims 36-39 are directed to "an isolated antibody that binds to an FIV antigen and an HIV antigen." Claims 40-42 are directed to "a method for detecting FIV infection in a human or animal that is susceptible to infection by FIV . . .." Claims 43 and 44 are directed to "a composition comprising a polynucleotide that encodes: a) an FIV protein, or a fragment thereof; and b) an HIV protein, or a fragment thereof." Claims 45 and 46 are directed to a composition comprising an FIV protein and an HIV protein. Thus, as can be seen from the brief summary of the claims presented above, there are eight independent claims (each of which has further dependent claims) and only one of which is directed to "a method for inducing an immune response" to an FIV. The Examiner's remarks under this rejection do not address anything concerning Applicants' claims directed to a method for inducing an immune response against HIV, or the methods for treating or preventing FIV or HIV infection in a human or an animal that is susceptible to infection by FIV, or to an antibody that binds an FIV antigen and an HIV antigen, or to the method of detecting FIV infection, or to the polynucleotide or protein composition claims. Thus, Applicants take the Examiner's remarks in the outstanding Office Action to be directed only to the claims that concern "a method for inducing an immune response to feline immunodeficiency virus in a human or an animal that is susceptible to infection by FIV," *i.e.*, claims 1-7.

In regard to pending claims 1-7, Applicants note that the claims specify that the immune response is generated in a human or a non-feline animal that is susceptible to infection by FIV. Prior to Applicants' surprising discovery, those of ordinary skill in the art did not believe or did not know that FIV could infect non-feline animals such as humans. There was no teaching or suggestion in the art that any animal other than a feline animal could be infected with FIV. Even if there was an indirect suggestion in the WO 94/02613 publication that FIV could infect non-felines, by way of reference to "a mammal," this was mere speculation and not supported by any data or other evidence. In fact, the WO 94/02613 publication even supports this by stating at page 2, lines 1-2, of the cited publication that "FIV does not appear to be capable of cat to human transmission." Thus, Applicants

respectfully assert that at the time of the present invention, there was no motivation in the art to induce an immune response to FIV in a human or other non-feline animal because humans and non-feline animals were not considered by the ordinarily skilled artisan to be susceptible to infection by FIV.

Moreover, Applicants respectfully submit that there is no teaching in the disclosure of the WO 94/02613 publication of treatment or prevention of FIV infection in cats. The WO 94/02613 publication teaches only the preparation of FIV polypeptides, *e.g.*, a modified FIV envelope protein. There is no data presented in the WO 94/02613 publication directed to immunizing cats (or any other animals) with an FIV immunogen. In fact, there is no data presented in the WO 94/02613 showing that a protective immune response, or even a humoral or cellular immune response, could be raised against the FIV polypeptides in cats or non-feline animals. As of the filing date of the WO 94/02613 application, it is stated therein (see page 1, third paragraph) that "there are as yet no reports in the literature of successful immunisation of cats against FIV infection using a subunit or peptide-based vaccine." Moreover, Applicants note that it does not appear that a corresponding U.S. patent ever issued from the WO 94/02613 application. As noted above, the WO 94/02613 publication does not teach or suggest, nor does it provide a reasonable expectation of success in treating or preventing FIV infection in cats or non-feline animals.

Applicants also note that amended dependent claim 4 further specifies that the FIV immunogen induces an immune response against two or more subtypes of FIV. There is no teaching or suggestion in the WO 94/02613 publication regarding inducing an immune response against two or more subtypes of FIV. In addition, dependent claim 6 specifies that the FIV immunogen is one that comprises an epitope that is evolutionarily conserved between FIV and HIV. It is only Applicants' disclosure that teaches that there are evolutionarily conserved epitopes between FIV and HIV proteins. Thus, Applicants respectfully assert that claims 1-7 are not obvious over the cited WO 94/02613 publication.

As noted above, Applicants have assumed that the Examiner intended his remarks and the rejection to apply only to claims 1-7 of the subject application. However, in the event that the Examiner intends the rejection apply against all the claims, including claims 8-46, Applicants submit the following remarks. In addition, should the Examiner apply the WO 94/02613 publication against

claims 8-46, Applicants respectfully request that the Examiner explain in a further Action how the cited publication teaches or suggests each and every element of the claims.

In regard to claims 8-14, directed to a method for inducing an immune response to HIV in a human by administering an FIV immunogen to that human, Applicants respectfully assert that there is no teaching or suggestion in the WO 94/02613 publication of a method of inducing an immune response to HIV in a human by using an FIV immunogen. Thus, the cited publication does not render claims 8-14 obvious.

In regard to claims 15-46, directed to a method for treating or preventing FIV infection in a non-feline animal that is susceptible to infection by FIV, Applicants respectfully assert that the WO 94/02613 publication clearly does not teach or suggest treatment or prevention of FIV infection in human or other non-feline animals because at the time of Applicant's invention, those skilled in the relevant art did not know or did not believe that non-feline animals such as humans could be infected with FIV. Similarly, there is no teaching or suggestion in the WO 94/02613 publication concerning the use of an FIV immunogen to treat or prevent infection by HIV in a human.

There is also no teaching or suggestion in the WO 94/02613 publication that an antibody that binds to an FIV antigen can cross react with an antigen of HIV. Applicants were the first to show that antibodies from people that are infected with FIV, but that are HIV negative, cross react with HIV antigens and, therefore, those antibodies can result in false positives when sera from the FIV infected person is screened using an HIV antibody-based assay.

In view of the above remarks, Applicants respectfully asserts that the cited WO 94/02613 publication does not teach or suggest Applicants' claimed invention, and fails to provide an ordinarily skilled artisan with any motivation to modify the prior art to arrive at Applicants' claimed invention. Accordingly, Applicants respectfully assert that the claimed invention is not obvious over the cited publication. Reconsideration and withdrawal of the rejection under 35 USC §103(a) is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

Doran R. Pace
Patent Attorney
Registration No. 38,261
Phone No.: 352-375-8100
Fax No.: 352-372-5800
Address: 2421 N.W. 41st Street, Suite A-1
Gainesville, FL 32606-6669

DRP/sl
Attachments: Replacement pages 21, 24, and 34-37; Marked-Up Version of Amended Claims.

homology) which were being produced in our laboratory (Figure 4, amino acid sequences shown). Thus, the sequences derived from subject #FH1 and her cat, were not due to contamination from laboratory strains of FIV. These sequences had <55% nucleotide and amino acid sequence homologies to HIV-1, HIV-2, HTLV, SIV, EIAV, CAEV, VV, FeLV, and FeFV and were clearly distinct from the primate, ungulate, and other feline retroviruses (data not shown). Furthermore, BLAST analysis against NCBI/GenBank indicated that no known human protein sequences had any significant degree of homology to FIV Gag protein.

Since subject #FH2 has previously worked with HIV-1, she was tested for HIV-1 infection by PCR and HIV-1 antibodies by commercial HIV-1 Western blot analysis upon request by the subject. Based on standard HIV-1 Western blot analyses using Cambridge Biotech (20-hour serum incubation) and Bio-Rad Laboratories (30-minute serum incubation) tests, this subject was negative for HIV-1 antibodies. This finding was also confirmed by a licensed diagnostic laboratory. However, upon longer incubation period (20 hours) on Bio-Rad Western blot strip, faint antibody reactivity to p24 was observed repeatedly using serum collected from subject #FH2 on two different days in 2001 but slightly stronger reactivity to p24 was detected in serum collected after 1993. Both direct and coculture amplified PBMC from subject #FH2 were negative for HIV-1 by both PCR and RT-PCR with HIV-1 p24 *ca* primers. This result was confirmed by a licensed diagnostic laboratory using RT-PCR (Roche Amplicore HIV-1 Monitor Test). Sera from #FH2 were next tested for the presence of antibodies to FIV proteins. The more recent sera were strongly positive for antibodies reactive to FIV p10, p24, and p65 (potential FIV RT protein) and weakly positive for antibodies reactive to FIV p55 by Western blot analysis (Figures 1A-D). Her sera from 1993, collected before her participation in HIV research, reacted weakly to p55 of FIV-Petaluma (FIV_{Pet}), FIV-Shizuoka (FIV_{Shi}) and FIV-Bangston (FIV_{Bang}) and reacted strongly to all FIV p24 and p10. This observation together with our Gag/*gag* sequence results suggests that this subject is actively or defectively infected with FIV. In order to determine the source of FIV infection, her pet cat #FC2 was tested for FIV. Cat #FC2 was negative for FIV infection by RT and PCR and for FIV antibodies by Western blot analysis

μg of UV-inactivated virus or cell lysate directly on the immunoblot strips with the serum for 2 hr and the immunoblots were developed as before. FIV-infected (FIV_{Shi}-infected FeT-J and FIV_{Bang}-infected FeT-J cell combination), HIV-infected ($HIV\text{-}1_{UCD1}$ infected HuT-78 and $HIV\text{-}1_{LAV}$ infected H9 cell combination) and uninfected (FeT-J alone or HuT-78/H9 combination) cells were inactivated by 0.6% paraformaldehyde. HIV-infected cells were also UV-inactivated before paraformaldehyde treatment. IgG levels of the cell-absorbed and unabsorbed mock sera were determined by commercial feline IgG radial-immunodiffusion assay (Bethyl Laboratory, Montgomery, Texas).

Cellular Immune Response: Virus-specific cellular immune responses of PBMC from vaccinated cats were determined by measuring the amount of interferon-γ produced in response to 10 μg/ml of recombinant FIV p24, $HIV\text{-}1_{BRU}$ p24, and $HIV\text{-}1_{IIIB}$ gp160 using the method previously described (Pu *et al.*, 1999). In addition, cells stimulated with uninfected cell lysate (20 μg/ml), SEA (0.2 μg/ml, positive control), media diluent (negative control), and purified whole FIV_{Pet} and FIV_{Shi} (20 μg/ml) were also included as additional controls.

Antibodies to FIV were developed in specific pathogen free (SPF) cats by either active infection with FIV strains or immunization with inactivated FIV vaccines. Sera from 41 FIV-infected cats at different time post-FIV inoculation were evaluated on BioRad $HIV\text{-}1_{UCD1}$ and Cambridge Biotech $HIV\text{-}1_{IIIB}$ immunoblots (Table 1, Figure 6A). Overall, 18 of 41 (44%) infected cats had antibodies to HIV-1 core capsid p24, matrix p18, Gag p55, intergrase p32, transmembrane envelope gp41, surface envelope gp120 or precursor envelope gp160 (Table 1, Figure 6A) with greatest reactivity to p24. Three of 10 cats infected with FIV_{Pet} (subtype A), 7 of 11 cats infected with FIV_{UK8} (subtype A), 5 of 11 cats infected with FIV_{Bang} (subtype A_{gag}/B_{env}), and 3 of 9 cats infected with FIV_{Shi} (subtype D) had cross-reactive antibodies to HIV-1. The majority of the cats (64%) infected with FIV_{UK8} developed cross-reactive antibodies to HIV-1, while only three cats (30%) infected with FIV_{Pet} developed cross-reactive antibodies to HIV-1. Both of these strains are subtype A FIV strains. Hence, strain specific cross-reactivity to HIV-1 may exist.

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U.S. Patent No. 5,846,825

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Marked-Up Version of Amended Claims

Claim 1 (amended):

1. A method for inducing an immune response to a feline immunodeficiency virus (FIV) in a human or [an] a non-feline animal that is susceptible to infection by FIV, said method comprising administering an effective amount of an FIV immunogen to said human or non-feline animal to induce said immune response.

Claim 4 (amended):

4. The method according to claim 1, wherein said FIV immunogen induces an immune response against more than one [or more subtypes] subtype of FIV.

Claim 11 (amended):

11. The method according to claim 8, wherein said FIV immunogen induces an immune response against more than one [or more subtypes] subtype of FIV.

Claim 15 (amended):

15. A method for treating or preventing feline immunodeficiency virus (FIV) infection in a human or [an] a non-feline animal that is susceptible to infection by FIV, said method comprising administering an FIV immunogen to said human or non-feline animal.

Claim 16 (amended):

16. The method according to claim 15, wherein said FIV immunogen induces an immune response against more than one [or more subtypes] subtype of FIV.

Claim 30 (amended):

30. The method according to claim 29, wherein said FIV immunogen induces an immune response against more than one [or more subtypes] subtype of FIV.

Claim 40 (amended):

40. A method for detecting FIV infection in a human or animal that is susceptible to infection by FIV, comprising detecting the presence of:

a) an antibody or antibodies that specifically bind to an FIV protein or peptide; or

b) nucleotide sequences of FIV.